

CLAIMS

1. A combination vaccine comprising antigens for protecting a subject against at least diphtheria ('D'), tetanus ('T'), pertussis ('P') and *Haemophilus influenzae* type b ('Hib'), wherein: (a) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; (b) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$; and (c) the Hib conjugate has never been lyophilised.
2. A vial having a piercable seal and containing a combination vaccine, which combination vaccine comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'), wherein the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide, and wherein: (a) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$, and (b) the vial's piercable seal has not been pierced.
3. A hermetically-sealed container containing a combination vaccine comprising antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'), wherein the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide, and wherein the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$.
4. A process for preparing a combination vaccine comprising antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'), wherein the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide, and the concentration of Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$, characterised in that the process does not include one or both of the following steps: (a) a step of lyophilisation of the Hib conjugate antigen; (b) a step of packaging the diphtheria, tetanus and pertussis antigens in admixed form separately from the Hib conjugate antigen.
5. A process for inserting a combination vaccine into a container, wherein: (a) the vaccine that comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'); (b) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; and (c) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$.
6. A process for attaching a label to a container, wherein: (a) the container contains a combination vaccine that comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'); (b) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; and (c) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$.
7. A process for inserting a combination vaccine into a container and then extracting the vaccine from the container, wherein: (a) the vaccine comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H.influenzae* type b ('Hib'); (b) the antigen for protecting

against Hib is a conjugate of a Hib capsular saccharide; and (c) the concentration of the Hib conjugate in the vaccine is <15 µg/ml.

- 5 8. A combination vaccine comprising antigens for protecting a subject against at least diphtheria ('D'), tetanus ('T'), pertussis ('P') and *H.influenzae* type b ('Hib'), wherein: (a) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; (b) the concentration of the Hib conjugate in the vaccine is <15 µg/ml; and (c) the vaccine (i) does not contain an aluminium hydroxide adjuvant and/or (ii) does not contain an aluminium potassium sulphate adjuvant.
9. The vaccine of claim 8, comprising an aluminium phosphate adjuvant.
- 10 10. The vaccine of claim 9, wherein the Hib conjugate is not adsorbed to the aluminium phosphate adjuvant.
11. The vaccine, vial, container or process of any preceding claim, where the diphtheria antigen comprises a diphtheria toxoid, the tetanus antigen comprises a tetanus toxoid, and the pertussis antigen comprises a cellular pertussis component.
12. The vaccine, vial, container or process of any preceding claim, where the conjugate comprises a CRM₁₉₇ carrier, a tetanus toxoid carrier or an outer membrane complex of *N.meningitidis* carrier.
- 15 13. The vaccine, vial, container or process of any preceding claim, where the conjugate comprises an oligosaccharide fragment of the Hib polyribosylribitol phosphate.
14. The vaccine, vial, container or process of any preceding claim, wherein the combination vaccine further comprises a surface antigen from hepatitis B virus.
- 20 15. The vaccine, vial, container or process of any preceding claim, wherein the combination vaccine further comprises a polio antigen.
16. A method for raising an antibody response in a mammal, comprising administering the vaccine of any preceding claim to the mammal.